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The time period for reply, if any, is set in the attached communication.

RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KARL BRUCE THOR

Appeal 2008-2979
Application 10/049,427
Technology Center 1600

Oral Hearing Held: January 13, 2009

Before TONI R. SCHEINER, ERIC B. GRIMES, and
MELANIE L. McCOLLUM, *Administrative Patent Judges*.

ON BEHALF OF THE APPELLANT:

GARY J. CONNELL, ESQUIRE
Sheridan Ross, PC
1560 Broadway
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32 The above-entitled matter came on for hearing on Tuesday, January
33 13, 2009, commencing at 1:02 p.m., at the U.S. Patent and Trademark
34 Office, 600 Dulany Street, Alexandria, Virginia, before Dawn A. Brown,
35 Notary Public.

PROCEEDINGS

2 THE USHER: Calendar Number 15, Appeal Number 2008-2979, Mr.
3 Connell.

4 JUDGE SCHEINER: Would you like to introduce your colleagues
5 for the record?

6 MR. CONNELL: This is Dr. Nadine Chien. She is the representative
7 of the applicant. And Mr. Joseph Kentoffio with J&J.

8 JUDGE SCHEINER: Whenever you're ready, you'll have 20 minutes.

9 MR. CONNELL: Okay. Good afternoon. I'd like to start just by
10 referencing claim 37, which is the broadest independent claim.

11 And claim 37 is generally directed toward a method of treating
12 premature ejaculation by administering on an as-needed basis the compound
13 dapoxetine. The claim further recites that administration of dapoxetine is
14 effective for treating that condition in the absence of the priming doses.

15 The sole rejection in this case concerns a combination of four
16 references. The two primary references are McMahon and Lane with
17 secondary references being Robertson and a patent by Ely Lilly referred to
18 as the Lilly reference.

19 JUDGE SCHEINER: May I interrupt you right away before you get
20 started?

21 MR. CONNELL: Sure.

22 JUDGE SCHEINER: Let's talk about what this claim really means by
23 it is effective for treating or managing premature ejaculation in the absence
24 of priming doses. Do you interpret that claim to mean that the method

1 requires no priming doses or that the dose is effective whether or not you
2 have priming doses? Because those are two different things.

3 MR. CONNELL: The latter. The dose is effective in the absence of
4 priming doses.

5 JUDGE SCHEINER: I'm sorry. Please continue.

6 MR. CONNELL: I'll continue. So much of the prosecution focused
7 on what the McMahon reference taught, what it conveyed to a person skilled
8 in the art, and there is a lot of detail in the file history that I won't review at
9 this time.

10 But I would like to focus on the term "as-needed." That term does
11 appear in claim 37 in that the administration is on an as-needed basis. So the
12 point that I would like to make is that this term "as-needed" has no definite
13 or fixed meaning that would be the same in all contexts.

14 JUDGE SCHEINER: Has no fixed meaning that is the same in all
15 contexts?

16 MR. CONNELL: That is correct. So to understand what this term
17 means in the context of claim 37, it is important to look at the specification.

18 So if we start with page 19 of the specification, it provides a definition
19 of that term and generally refers to administration of a therapeutically
20 effective amount at a time interval that is sufficient to provide a proved
21 therapeutic profile while avoiding priming doses, chronic administration and
22 overdosing.

23 And I'll also note that during prosecution, claim 37 was amended to
24 include a limitation wherein the administration of dapoxetine is effective for
25 treating or managing premature ejaculation in the absence of priming doses.

1 Further, I think it is important to note and understand what a priming
2 dose is. And so while we believe that that is a term that is well understood
3 by those in the field, during prosecution in the submission of the declaration
4 by Dr. David Rivas, Dr. Rivas stated what as a skilled person he understood
5 that to mean, which is prior dose of a drug that has not been cleared from the
6 body at the time of administration of a subsequent dose.

7 And so all of those elements, I think, give good understanding of what
8 that term "as-needed" means in the context of claim 37.

9 JUDGE SCHEINER: Okay.

10 MR. CONNELL: Turning to McMahon, the McMahon reference, we
11 look at study 1 of the McMahon reference. First of all, I'll also note that the
12 title of McMahon is Treatment of Premature Ejaculation with Paroxetine as
13 Needed. So McMahon as well as our claim refers to as-needed
14 administration.

15 So if we look in McMahon at study 1 -- there are two studies. Study 1
16 is the arm that he refers to as being "as needed." And on page 1827 of
17 McMahon, the study protocol is provided.

18 And that protocol has subjects being instructed to take either the drug
19 or a placebo, which they're taking, three to four hours before intercourse.

20 It is also important to note that there is no limitation on a time interval
21 between intercourse events and, therefore, it is possible and, in fact,
22 McMahon even recognized that it does happen that you get higher
23 Paroxetine concentrations as subsequent doses of the drug are taken.

24 JUDGE SCHEINER: Is there anything to indicate that you don't get
25 an improved result without the subsequent doses?

26

1 MR. CONNELL: Yes, there is. So -- no, I guess maybe a better way
2 to say that is there is no data in McMahon that shows that you get effective
3 treatment without priming doses.

4 JUDGE SCHEINER: What about the week 1 studies?

5 MR. CONNELL: Okay. Yeah. So let me get to week 1 and let me
6 just make one final comment there. So McMahon does in the study 1 data
7 refer to -- on page 1829 there is a passage that says as you get subsequent
8 doses, you build up Paroxetine levels and get an accumulation in greater
9 response.

10 And I can just point you to that passage. As I said, it is on page 1829
11 at the second column near the top, the third line down, the sentence
12 beginning with, "Therefore, as Paroxetine concentration increases with
13 multiple dosing, the metabolic enzyme activity decreases, and therefore, it
14 prolongs drug clearance and results in disproportionate increase of
15 concentration with every dose."

16 So to address your question, then, about the week 1 data, that is the
17 second point that I would like to address. And this is an important point
18 because it is -- the examiner's position, I think, in large part hinges on
19 interpretation of that data point.

20 So if we look at figure 1, which appears on page 1828 of the
21 reference, that -- this is the study 1 data, and the question is whether the data
22 in week 1, which you can see the placebo there is the triangle, the square is
23 the Paroxetine, and the Paroxetine square is higher than the triangle.

24 But the question is whether that data point shows effective, as-needed
25 dosing in the absence of priming doses. And the examiner's position is that

1 it does, in fact, show that. And the examiner points to figure 1, for example,
2 and says, look, you can see that with Paroxetine you're getting some effect.

3 Our position, however, relies on some other points that I'll now make.
4 If we look, for example, on page 1827 of McMahon, McMahon states that in
5 weeks -- and this is the sentence that bridges columns 1 and columns 2, that
6 the ejaculatory latency of groups A and B during treatment with Paroxetine
7 as needed --

8 JUDGE SCHEINER: I'm sorry. You said where was that bridging
9 column?

10 MR. CONNELL: The last sentence on --

11 JUDGE SCHEINER: Because we don't show columns in our -- our
12 copy of the reference doesn't show columns.

13 MR. CONNELL: Are you on the correct McMahon reference?

14 JUDGE SCHEINER: I sure hope so. Figure 1 does show what you're
15 saying.

16 JUDGE GRIMES: The record copy is apparently something that was
17 downloaded from the internet.

18 MR. CONNELL: Okay. So it is in the first paragraph of the result
19 section.

20 JUDGE SCHEINER: Study 1, mean patient age, is that where you
21 are?

22 MR. CONNELL: Yeah. So near the bottom of that first paragraph, in
23 fact the last sentence of that paragraph, begins with the ejaculatory latency
24 time. Are you there?

25 JUDGE SCHEINER: Yes.

1 MR. CONNELL: The ejaculatory latency time for groups A and B
2 during treatment with Paroxetine as needed was statistically superior to the
3 placebo at two, three and four weeks.

4 So what this means -- and note that he does not say that it is
5 statistically superior at week 1. And so what this means is that the week 1
6 data was not statistically significantly better than placebo.

7 And as support for this, I would also direct you to the declaration of
8 Dr. Rivas that was submitted during prosecution, and that was in July 2006
9 in paragraph 3A.

10 JUDGE SCHEINER: Let me ask you this: It doesn't say that it was
11 statistically significant, so the inference is that it wasn't. But it shows some
12 improvement. Is it your position that there has to be a statistically
13 significant result to give any sort of suggestion?

14 MR. CONNELL: That is correct. In speaking with Dr. --

15 JUDGE SCHEINER: What is your basis for that?

16 MR. CONNELL: In speaking with Dr. Rivas, we talked with him a
17 lot about this particular point. And the way he explained it to me was that if
18 you look at those two data points in week 1, the fact that they are not
19 statistically significantly different means that they are within the margin of
20 error of each other. And so they --

21 JUDGE SCHEINER: Well, assuming that is true --

22 MR. CONNELL: So what that means is that those two points could
23 be right on top of each other, they could be like this or they can be like this.

24 JUDGE SCHEINER: No, no, no. I understand that, but you are
25 making -- drawing an inference from something that is not said so...

1 MR. CONNELL: Right. And so -- okay. On that point, the other
2 thing that I would say is that in the Rivas declaration there is evidence by his
3 statement as one skilled in the art that that is how he would interpret that
4 graph and that he would not rely on that as being statistically significant and
5 different.

6 JUDGE SCHEINER: So the position is really that one of skill
7 wouldn't interpret that as statistically significant and would not rely on it?

8 MR. CONNELL: That is correct.

9 JUDGE SCHEINER: Is that what you're saying?

10 MR. CONNELL: Right. And so an additional point in that regard is
11 also outlined in the Rivas declaration that there is no information in the
12 McMahon reference that would even allow a person skilled in the art to
13 determine whether there was statistical significance in those two data points
14 being different.

15 The first point that I would make about the week 1 data is that if you
16 look at the underlined numbers that are reflected in table 2, the number of
17 incidents of intercourse during that first week is greater than one, and so that
18 means that at least one person had at least multiple intercourse events, which
19 means that whoever that person was had multiple doses, and that could have
20 led to priming dose.

21 But again, there is no way to tell other than to know that there was a
22 possibility that within that week that happened.

23 JUDGE SCHEINER: We're getting close to the end of our time. Can
24 we talk about -- back up a little bit and talk about whether the propriety -- or
25 the examiner's conclusion that it would have been obvious to substitute, and
26 I'm going to pronounce this incorrectly, dapoxetine for Paroxetine?

1 MR. CONNELL: Right. Sure.

2 JUDGE SCHEINER: I mean, let's get a little more -- go back a little
3 bit to that basic contention.

4 MR. CONNELL: Okay. So looking more at the legal analysis. And
5 so we are in the realm of KSR, which came out after the appeal brief. So the
6 examiner's position was that the prior art showed a finite number of
7 identifiable solutions for which there was a reasonable expectation of
8 success. And our position is that that is not the case.

9 That that concept of looking at this situation is not the case because if
10 you look at the two primary references, McMahon and Lane, they generally
11 talk about three broad categories of compounds: Serotonergic drugs,
12 hypotrophic drugs and antidepressant drugs.

13 And the examiner actually relies on the disclosure in those two
14 references to show or to take the position that those drugs affect premature
15 ejaculation and sexual function.

16 JUDGE SCHEINER: Aren't we talking in all cases in all these
17 references specifically about selective serotonin reuptake inhibitors?

18 MR. CONNELL: Right. So both Paroxetine, which is the McMahon
19 reference, our compound Paroxetine is also an SSRI. So first of all, the
20 references and the examiner's reliance on those beyond SSRI's, although he
21 does focus down onto that class of compounds.

22 JUDGE SCHEINER: Which reference are you talking about now
23 because McMahon is clearly just one particular SSRI and Lane is also --

24 MR. CONNELL: Lane is a review of 92 articles, and so it talks about
25 SSRI's but also talks about antidepressants.

1 JUDGE SCHEINER: Doesn't Lane also say -- it is really small on my
2 screen right now -- that the use of low doses on as-needed basis prior to
3 intercourse is a possibility for SSRI's, such as fluvoxamine, Paroxetine and
4 sertraline, which have half lives of approximately one day or less. So --
5 okay.

6 MR. CONNELL: So I think if you get to the point in the analysis
7 where you're limiting yourself to the category of SSRI's, the other point that
8 is important to make and to note is that this class of compounds is very
9 diverse, and there are a lot of compounds within that class that have very
10 different properties. And that particularly, if you look at those compounds
11 in a structural basis --

12 JUDGE SCHEINER: But when you say "this class of compounds,"
13 you are talking about SSRI's now, not antidepressants in general?

14 MR. CONNELL: Yes. Even within the groups of SSRI's, if you look
15 at the structures of these compounds, they're very diverse. In fact, if you can
16 look at some of the post-KSR Federal Circuit case law, there are two cases
17 that I can point to. One is Takeda and the other is Esai versus Dr. Reddy.

18 And both of those describe pharmaceutical compounds which -- pairs
19 of pharmaceutical that are very similar structurally, but the Court found that
20 that was not sufficient structural similarity to support obviousness.

21 What I would say here is if you look at the structure of dapoxetine
22 versus Paroxetine versus fluvoxamine, all the SSRI's, they are very different
23 structurally, much more different than that.

24 And the other point that I would make is that the SSRI compounds, as
25 I mentioned before, just have a lot of different functions within -- or they
26 function differently. They can be very different from each other even

1 though they meet that functional qualification of being a selective serotonin
2 reuptake.

3 JUDGE SCHEINER: Okay.

4 MR. CONNELL: In fact, dapoxetine is the only compound across the
5 board that has been found to be effective on an as-needed basis without
6 priming doses.

7 JUDGE SCHEINER: Well, let me ask you this then. What do we
8 know from the -- the Robertson and Ely Lilly reference are the ones that
9 mention dapoxetine. That is correct, right?

10 MR. CONNELL: That is correct.

11 JUDGE SCHEINER: What do we know, if anything, from those
12 references about the way dapoxetine functions --

13 MR. CONNELL: -- functions.

14 JUDGE SCHEINER: Obviously, we can see the structure in the --

15 MR. CONNELL: So Robertson was the original patent on the
16 composition itself. It does identify dapoxetine as being an SSRI, just
17 disclosed it in the context of being a potential antidepressant, you know, the
18 whole family of Prozac.

19 The Ely Lilly reference is quite an odd reference. It discloses five
20 compounds, one of which is dapoxetine, for this enormous laundry list of
21 literally hundreds of different conditions that are varied.

22 And if you look at it and read through that, our position -- and the
23 examiner didn't really press this point -- is that it essentially has no -- does
24 not effectively disclose any particular use because there are so many. But it
25 does disclose sexual dysfunction.

1 JUDGE SCHEINER: Right. Okay. Well, I think -- do you have any
2 questions? Did you have anything further? We are running a little tight on
3 time.

4 MR. CONNELL: Okay. No. I think we got pretty much through all
5 the of the points I wanted to make. Thank you very much for your time.

6 JUDGE SCHEINER: Thank you for coming in.

7 (Whereupon, the proceedings at 1:24 p.m. were concluded.)

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